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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,072	03/12/2004	Martin John Glenton Hughes	2479.032000J	9134

26111 7590 07/31/2007

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	
MAIL DATE	**DELIVERY MODE**
07/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,072	HUGHES ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *20-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 4/25/07 has been entered into the record.

Status of claims

2. Claims 1-19 have been canceled.

New claims 20-49 have been added and are under examination

Claim Rejections - New 35 U.S. C. § 112, first paragraph necessitated by amendment

3. The written description rejection for newly added claims 20-21, 24-34, 35, 36, 39-49 under 35 U.5.C. 112, first paragraph is maintained for the same reasons as set forth in the previous office action.

New claims 20-21, 24-34, 35, 36, 39-49 are drawn to a method of preventing a Group B streptococcal disease or disorder in a subject comprising administering to a subject in need thereof an effective amount of a composition comprising an isolated peptide, which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13, wherein said peptide induces antibodies that specifically bind to a polypeptide consisting of SEQ ID NO: 13. wherein the infection is a Group B Streptococcal infection , wherein the infection is a local infection, wherein the infection is a urinary tract infection.

The broadly claimed method prevents a Group B streptococcal disease or disorder comprising administering a composition comprising variant polypeptide which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13.

The instant specification may provide an adequate written description of polypeptide which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13, the specification fails to disclose variant polypeptide which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13. (the examiner is going to refer variant of SEQ ID NO: 13 here after in the action) .

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it

does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims drawn to a Group B streptococcal disease or disorder comprising administering a composition comprising variant polypeptide which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13 such as those at issue here. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of variant of SEQ ID NO: 13, as per Lilly by structurally describing a representative number of variant or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus" have to disclosed. In this application such structural features common to the claimed variant have not been disclosed. Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." In this case, the specification does not disclose variant polypeptide that is used in the claimed method required to practice the claims in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of variant nor does the specification provide any partial structure of such variant, nor any

physical or chemical characteristics of the variant nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses a single isolated polypeptide set for th as SEQ.ID.NO:13 encoded by nucleic acid set forth as SEQ.ID.NO:14 and does not provide a description of variant polypeptide that would satisfy the standard set out in Enzo.

Thus, the specification also fails to describe the variant by the test set out in Lilly. Therefore, it necessarily fails to describe a "representative number" of such variants using to prevent infection. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Given that there is no teaching of the amino acids critical , for immunogenicity, i.e., preventing the disease , given the claimed invention is not defined by structure/ function which does not suffice to define the claimed genus, i.e., variant polypeptide SEQ.ID.NO:13.

In addition the art indicates that variety to genus polypeptides having 95% similar to SEQ.ID.NO:13 , however said polypeptides are 95-96% identical in structure with the claimed polypeptide having 95% similar to SEQ.ID.NO:13 and has no functional relationship . Thus there is no correlation between structure and function. This is an evidence for diversity of species.

```
8DXB8_STRA5
ID   Q8DXB8_STRA5   PRELIMINARY;   PRT;   482 AA.
AC   Q8DXB8;
DT   01-MAR-2003, integrated into UniProtKB/TrEMBL.
DT   01-MAR-2003, sequence version 1.
DT   07-FEB-2006, entry version 13.
DE   PTS system, IIC component, putative.
GN   OrderedLocusNames=SAG1933;
OS   Streptococcus agalactiae serotype V.
OC   Bacteria; Firmicutes; Lactobacillales; Streptococcaceae;
OC   Streptococcus.
OX   NCBI_TaxID=216466;
RN   [1]
RP   NUCLEOTIDE SEQUENCE [LARGE SCALE GENOMIC DNA].
RC   STRAIN=2603 V/R / ATCC BAA-611 / Serotype V;
RX   MEDLINE=22222988; PubMed=12200547; DOI=10.1073/pnas.182380799;
RA   Tettelin H., Masignani V., Cieslewicz M.J., Eisen J.A., Peterson S.N.,
RA   Wessels M.R., Paulsen I.T., Nelson K.E., Margarit I., Read T.D.,
RA   Madoff L.C., Wolf A.M., Beanan M.J., Brinkac L.M., Daugherty S.C.,
RA   DeBoy R.T., Durkin A.S., Kolonay J.F., Madupu R., Lewis M.R.,
RA   Radune D., Fedorova N.B., Scanlan D., Khouri H.M., Mulligan S.,
RA   Carty H.A., Cline R.T., Van Aken S.E., Gill J., Scarselli M., Mora M.,
RA   Iacobini E.T., Brettoni C., Galli G., Mariani M., Vegni F., Maione D.,
RA   Rinaudo D., Rappuoli R., Telford J.L., Kasper D.L., Grandi G.,
RA   Fraser C.M.;
RT   "Complete genome sequence and comparative genomic analysis of an
RT   emerging human pathogen, serotype V Streptococcus agalactiae.";
RL   Proc. Natl. Acad. Sci. U.S.A. 99:12391-12396(2002).
CC   ---------------------------------------------------------------------
CC   Copyrighted by the UniProt Consortium, see http://www.uniprot.org/terms
CC   Distributed under the Creative Commons Attribution-NoDerivs License
CC   ---------------------------------------------------------------------
DR   EMBL; AE014279; AAN00795.1; -; Genomic_DNA.
DR   TIGR; SAG1933; -.
DR   GO; GO:0016021; C:integral to membrane; IEA.
DR   GO; GO:0009401; P:phosphoenolpyruvate-dependent sugar phospho. . .; IEA.
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DR   InterPro; IPR013014; PTS_EIIC_2.
DR   InterPro; IPR004703; PTS_IIC_galc.
DR   InterPro; IPR001865; Ribosomal_S2.
DR   Pfam; PF03611; EIIC-GAT; 1.
DR   PROSITE; PS51104; PTS_EIIC_TYPE_2; 1.
DR   PROSITE; PS00962; RIBOSOMAL_S2_1; UNKNOWN_1.
KW   Complete proteome.
SQ   SEQUENCE   482 AA;  52159 MW;  D6FFE8B1F15D3E1D CRC64;

  Query Match             96.5%;  Score 598;  DB 2;  Length 482;
  Best Local Similarity   99.2%;  Pred. No. 6.6e-42;
  Matches  120;  Conservative    1;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MQVFLNIVNKFFDPVIHMGSGVVMLIVMTGLAMIFGVKFSKALEGGIKLAIALTGIGAII 60
              ||||||||||||||:||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MQVFLNIVNKFFDPIIHMGSGVVMLIVMTGLAMIFGVKFSKALEGGIKLAIALTGIGAII 60

Qy         61 GILTGAFSESLQAFVKNTGINLSIIDVGWAPLATITWGSPYTLYFLLIMLIVNIVMIVMK 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 GILTGAFSESLQAFVKNTGINLSIIDVGWAPLATITWGSPYTLYFLLIMLIVNIVMIVMK 120

Qy        121 K 121
              |
Db        121 K 121

Q3DIQ8_STRAG
ID   Q3DIQ8_STRAG   PRELIMINARY;   PRT;   160 AA.
AC   Q3DIQ8;
DT   22-NOV-2005, integrated into UniProtKB/TrEMBL.
DT   22-NOV-2005, sequence version 1.
DT   07-FEB-2006, entry version 4.
DE   PTS system, IIC component.
GN   ORFNames=SAL_1980;
OS   Streptococcus agalactiae 515.
OC   Bacteria; Firmicutes; Lactobacillales; Streptococcaceae;
OC   Streptococcus.
OX   NCBI_TaxID=342614;
RN   [1]
RP   NUCLEOTIDE SEQUENCE.
RC   STRAIN=515;
RX   PubMed=16172379; DOI=10.1073/pnas.0506758102;
RA   Tettelin H., Masignani V., Cieslewicz M.J., Donati C., Medini D.,
RA   Ward N.L., Angiuoli S.V., Crabtree J., Jones A.L., Durkin A.S.,
RA   DeBoy R.T., Davidsen T.M., Mora M., Scarselli M., Margarit y Ros I.,
RA   Peterson J.D., Hauser C.R., Sundaram J.P., Nelson W.C., Madupu R.,
RA   Brinkac L.M., Dodson R.J., Rosovitz M.J., Sullivan S.A.,
RA   Daugherty S.C., Haft D.H., Selengut J., Gwinn M.L., Zhou L., Zafar N.,
RA   Khouri H., Radune D., Dimitrov G., Watkins K., O'Connor K.J.,
RA   Smith S., Utterback T.R., White O., Rubens C.E., Grandi G.,
RA   Madoff L.C., Kasper D.L., Telford J.L., Wessels M.R., Rappuoli R.,
RA   Fraser C.M.;
RT   "Genome analysis of multiple pathogenic isolates of Streptococcus
RT   agalactiae: implications for the microbial 'pan-genome'.";
RL   Proc. Natl. Acad. Sci. U.S.A. 102:13950-13955(2005).
CC   -!- CAUTION: The sequence shown here is derived from an
CC       EMBL/GenBank/DDBJ whole genome shotgun (WGS) entry which is
CC       preliminary data.
CC   ---------------------------------------------------------------------
CC   Copyrighted by the UniProt Consortium, see http://www.uniprot.org/terms
CC   Distributed under the Creative Commons Attribution-NoDerivs License
CC   ---------------------------------------------------------------------
DR   EMBL; AAJP01000086; EAO70329.1; -; Genomic_DNA.
DR   GO; GO:0016021; C:integral to membrane; IEA.
DR   GO; GO:0009401; P:phosphoenolpyruvate-dependent sugar phospho. . .; IEA.
SQ   SEQUENCE   160 AA;  17663 MW;  5376AC2863A0F8E3 CRC64;

  Query Match             95.6%;  Score 593;  DB 2;  Length 160;
  Best Local Similarity   98.3%;  Pred. No. 6.5e-42;
```

```
  Matches  119;  Conservative    1;  Mismatches    1;  Indels    0;  Gaps    0;

Qy          1 MQVFLNIVNKFFDPVIHMGSGVVMLIVMTGLAMIFGVKFSKALEGGIKLAIALTGIGAII 60
              ||||||||||||||:|||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MQVFLNIVNKFFDPIIHMGSGVVMLIVMTGLAMIFGVKFSKALEGGIKLAIALTGIGAII 60

Qy         61 GILTGAFSESLQAFVKNTGINLSIIDVGWAPLATITWGSPYTLYFLLIMLIVNIVMIVMK 120
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||| |||
Db         61 GILTGAFSESLQAFVKNTGINLSIIDVGWAPLATITWGSPYTLYFLLIMLIVNIVMXVMK 120

Qy        121 K 121
              |
Db        121 K 121
```

Thus, the specification does not provide an adequate written description for a method of preventing a Group B streptococcal disease or disorder in a subject comprising administering to a subject in need thereof an effective amount of a composition comprising an isolated peptide, which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13, that is required to practice the claimed invention as discussed above.

Claims 20-21, 24-34, 35, 36, 39-49 do not comply with 35 USC 112, first paragraph because it is not supported by an adequate written description in the specification for the claimed method using variant of SEQ.ID.NO:13.

Applicant states that the claimed peptide comprising an amino acid sequence 95% similar to SEQ ID NO: 13 has both structural feature as well as a functional characteristic because *S. agalactiae* M732, and different strains of *Streptococcus agalactiae* (Group B *Streptococcus),* specifically binds to antibodies raised against a polypeptide consisting of SEQ ID NO: 13 as shown in Table 1.

The arguments have been considered but has not been found persuasive, Although an isolated polypeptide comprising an amino acid sequence at least 99% -100% similar to SEQ ID NO: 13, found in S. agalactiae M732 specifically binds to antibodies raised against a polypeptide consisting of SEQ ID NO: 13 as shown in Table 1, the claimed peptide comprising an amino acid sequence at least 95% similar to SEQ ID NO: 13 has not been shown to be recognizing strains of Streptococcus agalactiae or recognizing or binding to antibodies raised against a polypeptide consisting of SEQ ID NO: 13.

4. The enablement rejection of claims 20-49 under 35 U.S.C. 112, first paragraph is maintained for the same reasons as set forth in the previous office action .

New claims 20-21, 24-34, 35, 36, 39-49 are drawn to a method of preventing a Group B streptococcal disease or disorder in a subject comprising administering to a subject in need thereof an effective amount of a composition comprising an isolated peptide, which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13, wherein said peptide induces antibodies that specifically bind to a polypeptide

consisting of SEQ ID NO: 13. wherein the infection is a Group B Streptococcal infection , wherein the infection is a local infection, wherein the infection is a urinary tract infection.

The broadly claimed method prevents a Group B streptococcal disease or disorder comprising administering a composition comprising variant polypeptide which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13.

This is a full enablement rejection for the claimed method.

While the disclosure provides guidance how to make the claimed polypeptide SEQ ID NO: 13 encoded by the nucleic acid, SEQ.ID.NO:12 and how to treat infection caused by *S. agalactiae* , the specification fails to disclose variant of SEQ ID NO: 13 (95% similar to SEQ.ID.NO: 13) . Therefore, a method of preventing Group B streptococcal disease or disorder using said variant of SEQ ID NO: 13 is not yet known or taught by the disclosure.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The teaching of the specification cannot be extrapolated to enable the claims because the claims as broadly drawn include preventing Group B streptococcal disease or disorder using variant of polypeptide SEQ.ID.NO: 13. However, using such variant of polypeptide SEQ.ID.NO: 13 is sufficient for preventing broadly claimed Group B streptococcal disease or disorder is acknowledged to be unpredictable because the specification fails to disclose the critical residues that are important in a polypeptide SEQ.ID.NO: 13 that can be used to Group B streptococcal disease or disorder. The specification provides no information on the immunogenicity of variant or the ability of such to protect from Group B streptococcal disease or disorder. The specification fails to teach that the claimed variant is capable of generating a humoral or cellular immune response such that broadly claimed variant can prevent Group B streptococcal disease or disorder . The specification also fails to teach that the immune response to the variant polypeptide alone or in combination with adjuvants or carriers provides for a

protection against Group B streptococcal disease or disorder in any acceptable animal model. It is well recognized in the art, that it is unclear whether an antigen(s) derived from a pathogen will elicit protective immunity. Ellis, R.W. (Chapter 29 of "VACCINES" [Plotkin, 5.A. et al. (eds) published by W. B. Saunders company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.... and thus protect the host against attack by the pathogen". The specification fails to teach polypeptide alone or in combination with other antigens does in fact confer protection from Group B streptococcal disease or disorder as is requisite of a method of prevention. In the absence of teachings in the specification, the claims are not enabled for a method of preventing Group B streptococcal disease or disorder. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

The specification provides no working examples demonstrating (i.e., guidance) enablement for using variant of SEQ.ID.NO:13 in preventing Group B streptococcal disease or disorder. Since the specification does not teach how to make variant of SEQ.ID.NO: 13, the skilled artisan would not be able to use the claimed variant in a method for preventing Group B streptococcal disease or disorder. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

If applicants were able to overcome the rejection as set forth above, the claims still would be rejected under scope of enablement , while enabling for a method of treating *S. agalactiae* infection a subject comprising administering to a subject in need thereof an effective amount of a composition comprising an isolated peptide set forth as SEQ ID NO: 13, wherein said peptide induces antibodies that specifically bind to a polypeptide consisting of SEQ ID NO: 13 , wherein the infection is a local infection, wherein the infection is a urinary tract infection, does not reasonably enabled for a method of preventing a Group B streptococcal disease or disorder in a subject comprising administering to a subject in need thereof an effective amount of a composition comprising an isolated peptide, which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13, wherein said peptide induces antibodies that specifically bind to a polypeptide consisting of SEQ ID NO: 13. wherein the infection is a Group B Streptococcal infection , wherein the infection is a local infection, wherein the infection is a urinary tract infection.

Applicant states that in order to expedite the prosecution, all claims were canceled, rendering the rejection moot and newly claims have been fully enabled.
The arguments have been considered but has not been found persuasive because the specification still does not provide guidance how to use a peptide, which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13 either in a method of preventing a Group B streptococcal disease or disorder

Or in a method of treating disease or disorder in a subject as discussed in the above rejection

New Claim Rejections - 35 U.S. C. § 112, first paragraph based on the amendment

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

6. Claims 20-49 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation disease or disorder" claimed in Claims 20-49 has no clear support in the specification and the claims as originally filed. A review of the specification discloses support for infection . The suggested support at page 2, line 6 to page 4, line 37 and Example 6, page 6, line 35 to page 7, line 23. page 1,line 9 to page 3, line 6 is not found persuasive because there is nothing in the specification to suggest the specific disease or disorder. Further, there is no mention of Group B streptococcal disease or disorder. The subject matter claimed in claims 20-49 broadens the scope of the invention as originally disclosed in the specification.

Claim Rejections-35 U.5.C. 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 20-49 are rejected under 35 U.5.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the metes and bounds of the term "similar" is not clear.

9. In view of cancellation of claims, the rejection made under 35 U.S. C. § 112, second paragraph in the previous office action is moot.

Remarks

10 No claims are allowed. WO200292818-A2 teaches an isolated polypeptide comprising an amino acid sequence 96% identical to the polypeptide SEQ.ID.NO:13 but does not teach or suggest an isolated polypeptide set forth as SEQ.ID.NO:13.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time

policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600

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